UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,243	03/23/2005	Ellen Welch	10589-040	2977

20583 7590 02/26/2007

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
WHISENANT, ETHAN C	
ART UNIT	**PAPER NUMBER**
1634	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,243	WELCH ET AL.	
	Examiner	Art Unit	
	Ethan Whisenant, Ph.D.	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-3* is/are allowed.

6)☒ Claim(s) *4-6 and 9-19* is/are rejected.

7)☒ Claim(s) *7 and 8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

NON-FINAL ACTION

1. **Claim(s) 1-19** as originally filed 29 NOV 01 is/are pending in this application.

35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

> A person shall be entitled to a patent unless –
>
> **(a)** the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> **(e)** the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
> or
> **(e)** the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

CLAIM REJECTIONS UNDER 35 USC § 102

4. Claim(s) 9-10 and 13-18 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Beckmann et al. [US 6,458,538 (2002)].

Beckmann et al. teach a method of identifying a compound to be tested for its ability to prevent or treat a disease characterized by or associated with the presence of a premature stop codon in a gene comprising all of the limitations recited in Claim 9-10. As regards the limitation which reads "wherein the disease is familial hypercholesterolemia, osteogenesis imperfecta, cirrhosis, ataxia telangiectasia or a lysosomal storage disease," note Column 4 of wherein Beckmann et al. teach that the diseases to be treated with compounds discovered by their method include Tay Sachs disease (i.e. a lysosomal storage disease).

Claim 13 is drawn to an embodiment of the method recited in Claim 1,2,3, 4 ,5 ,9 or 10 wherein the reporter gene is selected from a defined group which includes green fluorescent protein, red fluorescent protein, β-galactosidase and alkaline phophatase. Beckmann et al., teach these limitation. See Column 17, beginning at about line 50.

Claim 14 is drawn to an embodiment of the method recited in Claim 1,2,3 or 9 wherein the cell is selected from a defined group which includes HeLa cells 3T3 cells . Beckmann et al., teach these limitation. See Column 5, beginning at about line 49.

Claim 15 is drawn to an embodiment of the method recited in Claim 4, 5 or 10 wherein the cell-free translation mixture is a cell-free extract selected from a defined group which includes HeLa cells. Beckmann et al., teach this limitation. See Column 5, lines 1-4.

Claim 16 is drawn to an embodiment of the method recited in Claim 1,2,3, 4 ,5 ,9 or 10 wherein the compound is selected from a defined group which includes peptoids, benzodiazepines and small organic molecule libraries. Beckmann et al., teach these limitation. See Column 13, beginning at about line 46 – Column 14 at about line 54.

Claim 17 is drawn to an embodiment of the method recited in Claim 16 wherein the small organic molecule libraries are selected from a defined group which includes libraries of benzodiazepines Beckmann et al., teach this limitation. See Column 13, beginning at about line 46 – Column 14 at about line 54.

Claim 18 is drawn to an embodiment of the method recited in Claim 1,2,3, 4 ,5 ,9 or 10 wherein the premature stop codon is UAG or UGA. Beckmann et al., teach these limitation. See for example Figure 5.

35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 USC § 102/103

7. Claim(s) 4, 13 and 15-19 is/are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Beckmann et al. [US 6,458,538 (2002)].

Beckmann et al. teach a method of identifying a compound that modulates premature translation termination or non-sense-mediated mRNA decay comprising all of the limitations recited in Claim 4 except these authors do not explicitly teach that the cell-free translation mixture is isolated from cells that have been incubated at about 0°C to about 10°C. However, note that Beckmann et al. teach that the cell – free translation lysate is prepared by the method disclosed by Jackson et al. [Methods in Enzymology 96 : 50-75 (1983)]. In the Jackson et al. method these authors teach collecting the rabbit blood from which the lysate is prepared in a chilled beaker which is in an ice bucket (i.e. at about 0°C to about 10°C). See the first paragraph on p. 56. Therefore, it asserted that the limitation in Claim 4 not taught by Beckmann et al. is in fact inherent to the method of Beckmann et al. in light of the teaching present in Jackson et al.

Claim 13 is drawn to an embodiment of the method recited in Claim 1,2,3, 4 ,5 ,9 or 10 wherein the reporter gene is selected from a defined group which includes green fluorescent protein, red fluorescent protein, β-galactosidase and alkaline phophatase. Beckmann et al., teach these limitation. See Column 17, beginning at about line 50.

Claim 15 is drawn to an embodiment of the method recited in Claim 4 , 5 or 10 wherein the cell-free translation mixture is a cell-free extract selected from a defined group which includes HeLa cells. Beckmann et al., teach this limitation. See Column 5, lines1-4.

Claim 16 is drawn to an embodiment of the method recited in Claim 1,2,3, 4 ,5 ,9 or 10 wherein the compound is selected from a defined group which includes peptoids, benzodiazepines and small organic molecule libraries. Beckmann et al., teach these limitation. See Column 13, beginning at about line 46 – Column 14 at about line 54.

Claim 17 is drawn to an embodiment of the method recited in Claim 16 wherein the small organic molecule libraries are selected from a defined group which includes libraries of benzodiazepines Beckmann et al., teach this limitation. See Column 13, beginning at about line 46 – Column 14 at about line 54.

Claim 18 is drawn to an embodiment of the method recited in Claim 1, 2, 3, 4 ,5 ,9 or 10 wherein the premature stop codon is UAG or UGA. Beckmann et al., teach these limitation. See for example Figure 5.

Claim 19 is drawn to an embodiment of the method recited in Claim 1, 2, 3, 4 ,5 ,9 or 10 wherein the premature stop codon context is UAGA, UAGC, UAGG, UAGU, UGAA, UGAC, UGAG or UGAU. Admittedly, Beckmann et al., do not explicitly teach these limitations. However, as evidenced by at least Figure 5 these limitations are inherent to Beckmann et al. in that when the stop codon is UAG it must necessarily be followed by one of U, A, C or G and when the stop codon is UGA it must necessarily be followed by one of U, A, C or G

CLAIM REJECTIONS UNDER 35 USC § 103

8. Claim(s) 5, 13 and 15-19 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Beckmann et al.[US 6,458,538 (2002)] in view of Kudlicki et al. [Analytical Biochemistry 206(2) : 389-393 (1992)].

Beckmann et al. teach a method of identifying a compound that modulates premature translation termination or non-sense-mediated mRNA decay comprising all of the limitations recited in Claim 5 except these authors do not teach that the cell extract be a S10 to S30 cell extract. However, Kudlicki et al. do teach a S30 cell extract. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to substitute the S30 cell extract of Kudlicki et al. for the RRL taught by Beckmann.

Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Claim 13 is drawn to an embodiment of the method recited in Claim 1,2,3, 4 ,5 ,9 or 10 wherein the reporter gene is selected from a defined group which includes green fluorescent protein, red fluorescent protein, β-galactosidase and alkaline phophatase. Beckmann et al., teach these limitation. See Column 17, beginning at about line 50.

Claim 15 is drawn to an embodiment of the method recited in Claim 4 , 5

or 10 wherein the cell-free translation mixture is a cell-free extract selected from a defined group which includes HeLa cells. Beckmann et al., teach this limitation. See Column 5, lines1-4.

Claim 16 is drawn to an embodiment of the method recited in Claim 1,2,3, 4 ,5 ,9 or 10 wherein the compound is selected from a defined group which includes peptoids, benzodiazepines and small organic molecule libraries. Beckmann et al., teach these limitation. See Column 13, beginning at about line 46 – Column 14 at about line 54.

Claim 17 is drawn to an embodiment of the method recited in Claim 16 wherein the small organic molecule libraries are selected from a defined group which includes libraries of benzodiazepines Beckmann et al., teach this limitation. See Column 13, beginning at about line 46 – Column 14 at about line 54.

Claim 18 is drawn to an embodiment of the method recited in Claim 1, 2, 3, 4 ,5 ,9 or 10 wherein the premature stop codon is UAG or UGA. Beckmann et al., teach these limitation. See for example Figure 5.

Claim 19 is drawn to an embodiment of the method recited in Claim 1, 2, 3, 4 ,5 ,9 or 10 wherein the premature stop codon context is UAGA, UAGC, UAGG, UAGU, UGAA, UGAC, UGAG or UGAU. Admittedly, Beckmann et al., do not explicitly teach these limitations. However, as evidenced by at least Figure 5 these limitations are inherent to Beckmann et al. in that when the stop codon is UAG it must necessarily be followed by one of U, A, C or G and when the stop codon is UGA it must necessarily be followed by one of U, A, C or G

9. **Claim(s) 6** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Beckmann et al.[US 6,458,538 (2002)] as applied against Claim 4 above and further in view of Kudlicki et al. [Analytical Biochemistry 206(2) : 389-393 (1992)].

Beckmann et al. teach a method of identifying a compound that modulates premature translation termination or non-sense-mediated mRNA decay comprising all of the limitations recited in Claim 6 except these authors do not teach that the cell extract be a S10 to S30 cell extract. However, Kudlicki et al. do teach a S30 cell extract. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to substitute the S30 cell extract of Kudlicki et al. for the RRL taught by Beckmann.

Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

10. Claim(s) 11-12 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Beckmann et al.[US 6,458,538 (2002)] as applied against Claim 4-5 and 9-10 above and further in view of Sabbadini [US 6,585,383 (2005)].

Beckmann et al. teach a method comprising all of the limitations recited in Claims 11-12 except these authors do not teach determining the structure of the compound identified as capable of suppressing premature translation termination or nonsense-mediated mRNA decay. However as evidenced by at least Sabbadini determining the structure of a candidate compound following it identification as useful in treating a particular disorder was well known at the time of the invention. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Beckmann et al. wherein a compound identified by the assays disclosed by Beckmann et al. is further analyzed to determine its structure. The motivation to make the modification recited above arises from the desire to understand the mechanism of the compound's activity thereby providing a starting point to identify other structurally similar compounds with improved properties over the lead compound.

REASON FOR ALLOWANCE

11. Claims 1-3 are allowable over the prior art of record because the prior art considered does not teach or reasonably suggest the methods of identifying a compound that modulates premature translation termination or non-sense mediated mRNA decay recited in Claims 1-3. In particular, the closest prior at Beckmann et al. [US Patent No. 6,458,538(2002)] do not teach or reasonably suggest, either alone or in combination with the other prior art considered, the methods of identifying a compound that modulates premature translation termination or non-sense mediated mRNA decay recited in Claims 1-3.

CLAIM OBJECTIONS

12. **Claim(s) 7-8** is /are objected to as being dependent upon a rejected base claim, but would appear to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

CONCLUSION

13. **Claim(s) 1-3** is/are allowable while Claim(s) 4-19 is/are rejected and/or objected to for the reason(s) set forth above.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM - 5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

The Central Fax number for the USPTO is (571) 273-8300. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

ETHAN WHISENANT
PRIMARY EXAMINER
Art Unit 1634